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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,091	02/05/2001	Dusan Pavcnik	PA-5213-CIP	2451
9896	7590	05/05/2004	EXAMINER	
COOK GROUP PATENT OFFICE P.O. BOX 2269 BLOOMINGTON, IN 47402			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 05/05/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/777,091

Applicant(s)

PAVCNIK ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-13,15,16 and 55-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7-12,15,16,55-58 and 60-65 is/are rejected.
- 7) ☒ Claim(s) 6 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 18, 2004 has been entered.

### ***Response to Amendment***

2. Applicants' cancellation of claims 14 and 17-54 in Paper No. 38 (Amendment F) is acknowledged.

### ***Claim Objections***

3. Claims 7, 60, and 61 are objected to because of the following informalities:

- a. Regarding claim 7, it depends on cancelled claim 3. Claim 9 depends on claim 7.
- b. Regarding claim 60, please (i) delete "an" (see line 1) and add --a-- in front of "blood vessel" (see line 1), and (ii) delete "elements" (see line 14 and line 17). Appropriate correction is required.
- c. Regarding claim 61, please add --the-- in front of "plurality" (see line 1) and add --of-- in front of "leaflets" (see line 1). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8, 64, and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Regarding claim 8, "said integral, one-piece member" lacks antecedent basis.
- b. Regarding claim 64, "the plurality of sides" (see line 4) lacks antecedent basis. Claim 65 depends on claim 64.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 5, 7-9, 12, 60, 61, and 63-65 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Andersen et al. (US 5,411,552; cited in Applicants' IDS).

As seen in Figures 1-3, Andersen et al. disclose an implantable valve comprising a self-expandable or balloon-expandable frame (stent 1; see column 2, lines 45-57; column 7, lines 21-

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23) having a plurality of bends (see Figures 1 and 2) and a plurality of leaflets (valve 6: made from either a biological material or a synthetic material) with inner edges defining an opening to permit fluid flow in a first direction and restricting fluid flow in a second opposite direction, and outer edges attached along one side element and adapted to sealingly engage the wall of the bodily passage (see entire document).

8. Claims 1, 2, 4, 5, 7-9, 12, 58, 60, and 63-65 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Moll et al. (US 6,287,334 B1; cited in Applicants' IDS).

As seen in Figures 1-6, Moll et al. disclose an implantable valve comprising a support frame (support frame 10) providing a plurality of side elements defining a path extending at least partially longitudinally along the wall and at least partially circumferentially around the wall (see Figures 1 and 2), and a plurality of leaflets (valve elements or blood flow stoppage elements 6) which inner edges define an opening to permit fluid flow in a first direction (see Figure 5) and engage each other to restrict fluid flow in a second opposite direction (see Figure 6). The outer edge of each one of the plurality of leaflets attached along one side element of said plurality of side elements (see Figure 1; see entire document). As seen in Figure 2, the frame can initially assume a generally flat configuration.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. Claims 10, 11, 55-57, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (US 5,411,552; cited in Applicants' IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS).

Andersen et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa. However, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Andersen et al., in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

11. Claims 10, 11, 55-57, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US 6,287,334 B1; cited in Applicants' IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS).

Moll et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa. However, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of

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using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Moll et al., in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

12. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (US 5,411,552; cited in Applicants' IDS) in view of Bessler et al. (US 5,855,601 A; cited in Applicant's IDS).

Andersen et al. disclose the invention as claimed except for disclosing the use of barbs to anchor the implantable valve to the wall of the bodily passage. However, the use of barbs/hooks to anchor stents to bodily passages is well known in the art. For example, Bessler et al. teach the use of a plurality of barbs 64 for holding a valve in place once it has been appropriately positioned (see Figures 6 and 7; see column 5, lines 12-14; column 5, line 67 to column 6, line 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a plurality of barbs, as taught by Bessler et al., with the valve of Andersen et al., in order to hold the valve in place once it has been appropriately positioned.

13. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US 6,287,334 B1; cited in Applicants' IDS) in view of Bessler et al. (US 5,855,601 A; cited in Applicant's IDS).

Moll et al. disclose the invention as claimed except for disclosing the use of barbs to anchor the implantable valve to the wall of the bodily passage. However, the use of barbs/hooks to anchor stents to bodily passages is well known in the art. For example, Bessler et al. teach the use of a plurality of barbs 64 for holding a valve in place once it has been appropriately

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positioned (see Figures 6 and 7; see column 5, lines 12-14; column 5, line 67 to column 6, line 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a plurality of barbs, as taught by Bessler et al., with the valve of Moll et al., in order to hold the valve in place once it has been appropriately positioned.

#### ***Response to Arguments***

14. Regarding 102(e) rejection over Moll et al. '334, Applicant's arguments filed February 18, 2004 have been fully considered but they are not persuasive. As seen in Moll et al. '334 Figure 6, fluid will be trapped between the leaflet(s) and the inner wall of the bodily passage. The area referred by the Examiner is the area between the leaflet(s) and the top part of the frame. Because of the curved structure formed by the leaflets, fluid will be trapped between said curved structure and the inner wall of the bodily passage.

#### ***Allowable Subject Matter***

15. Claim 59 is allowed.

16. Claims 6 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



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*Conclusion*

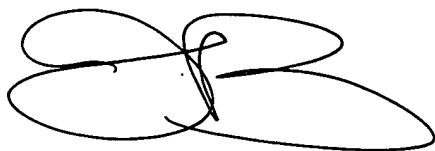
17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Thorpe et al. (US 2003/0130726 A1) and Xie et al. (US 2003/0181974 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



May 1<sup>st</sup>, , 2004



David H. Willse  
Primary Examiner